

Docket No.: 02755/0205241-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Benjamin Oshlack *et al.*

Application No.: 10/731,678

Confirmation No.: 4265

Filed: December 8, 2003

Art Unit: 1615

For: ORALLY ADMINSTRABLE OPIOID
FORMULATIONS HAVING EXTENDED
DURATION OF EFFECT

Examiner: M. Fitzgerald

**PETITION TO CORRECT INVENTORSHIP OF
NON-PROVISIONAL APPLICATION UNDER 37 C.F.R. § 1.48(c)**

MAIL STOP PETITION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a petition under 37 C.F.R. § 1.48(c) to correct the inventorship of the above-captioned non-provisional application to add the name of Frank Pedi, Jr. as an inventor of the subject matter claimed in this application. This petition is accompanied by: (1) a statement of Frank Pedi, Jr., the person being added as a co-inventor; (2) a Declaration and Power of Attorney signed by each of the inventors Benjamin Oshlack, Mark Chasin, and Frank Pedi Jr.; (3) a written statement of Philip C. Strassburger, Vice President of Intellectual Property for Purdue Pharma L.P. (the assignee of this application), consenting to the change of inventorship; and (4) a statement under 37 C.F.R. § 3.73(b).

A Fee Transmittal Form is also submitted herewith, along with payment of the estimated processing fee required under 37 C.F.R. § 1.17(i). The Commissioner is hereby

Petition to Correct Inventorship

Application No. 10/731,678
(Docket No. 02755/0205241-US0)

authorized and requested to charge any deficiency in the submitted fee or to charge any excess to
Deposit Account No. 04-0100 of Applicants' undersigned attorneys/agents.

* * * * *

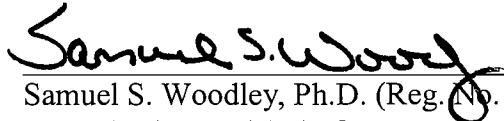
REMARKS

This application was originally filed identifying only Benjamin Oshlack and Mark Chasin as inventors. However, Applicants' subsequent amendments to the claims in this application have necessitated the addition of Frank Pedi, Jr. as a named inventor of the subject matter presently claimed in this application. Applicants therefore respectfully request that the named inventorship be amended, to add the name of Frank Pedi, Jr. A signed Statement by the added inventor Frank Pedi, Jr. accompanies this Petition. As explained in that Statement, the addition of Mr. Pedi as an inventor is necessitated by amendments to the claims of this application. Mr. Pedi's Statement also explains that this inventorship error occurred without any deceptive intention on his part.

A Fee Transmittal Form also accompanies this Petition, with payment of the estimated fee required under 37 C.F.R. § 1.17(i). The Commissioner is hereby authorized and requested to charge any deficiency in the submitted fee or to charge any excess to Deposit Account No. 04-0100 of Applicants' undersigned attorneys/agents.

Respectfully submitted,

Dated: April 20, 2007


Samuel S. Woodley, Ph.D. (Reg. No. 43,287)
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant

Attachments:

Tab 1: Statement of Frank Peddi, Jr. In Support of Petition Under 37 C.F.R. § 1.48(c) To Correct Inventorship;

Tab 2: Declaration and Power of Attorney executed by the inventors Benjamin Oshlack, Mark Chasin and Frank Pedi, Jr.;

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Tab 3: Consent of Assignee in Support of Petition to Correct Inventorship Pursuant to 37 C.F.R. § 1.48(c); and

Tab 4: Statement Under 37 C.F.R. § 3.73(b), with attached assignment documents.

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Examiner: M. Fitzgerald

**STATEMENT OF FRANK PEDI, JR. IN SUPPORT OF
PETITION UNDER 37 C.F.R. § 1.48(C) TO CORRECT INVENTORSHIP**

MAIL STOP PETITION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Frank Pedi, Jr., hereby declare and state as follows:

1. I am a citizen of the United States of America and am more than twenty-one (21) years of age. I presently reside at the address in city of Yorktown Heights in the state of New York.

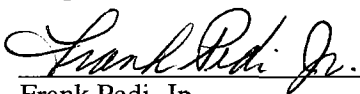
2. I have read and am familiar with the above-captioned patent application, including the original claims as filed in the U.S. Patent and Trademark Office (the "USPTO"). I understand that the application was originally filed naming only Benjamin Oshlack and Mark Chasin as inventors. In particular, the application as filed did not name or identify me as an inventor.

3. It is my understanding that the claims of this application have been amended since its filing in the USPTO. A copy of what I understand to be the currently pending claims of the application is attached to this Statement, at Tab 1. I have read and am familiar with these pending claims.

4. I hereby declare that the addition of my name as an inventor of this application is necessitated by the amendment(s) to the claims, and that the omission of my name as an inventor occurred without any deceptive intent on my part.

5. I further declare that all statement made herein of my own knowledge are true; that all statement made on information and belief are believed to be true. I understand that willful false statement and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or of any patent issuing therefrom.

Dated: 04/05/07

Respectfully submitted,

Frank Pedi, Jr.

Attachments:

Exhibit 1: Pending Claims.

EXHIBIT 1

EXHIBIT 1: PENDING CLAIMS

80. A sustained-release dosage form, comprising oxymorphone or a salt thereof, a hydrophilic polymer, a binder, and a diluent.
81. The sustained-release dosage form of claim 80, wherein the dosage form contains granules having a diameter from about 0.1 mm to about 3 mm.
82. The sustained-release dosage form of claim 80, further comprising an alkylcellulose.
83. The sustained-release dosage form of claim 80, further comprising ethylcellulose.
84. The sustained-release dosage form of claim 80, wherein the dosage form is in the form of a tablet.
85. The sustained-release dosage form of claim 80, wherein the dosage form is in the form of a capsule.
86. The sustained-release dosage form of claim 80, wherein the dosage form is in the form of a matrix.
87. The sustained-release dosage form of claim 80, wherein the dosage form provides a therapeutic effect for about 12 hours or more.
88. The sustained-release dosage form of claim 80, wherein the dosage form provides a therapeutic effect for about 24 hours or more.
89. A sustained-release dosage form, made by the process comprising: (a) mixing oxymorphone or a salt thereof with a hydrophilic polymer, a binder, and a diluent; (b)

subjecting the mixture to shear to form granules; and (c) incorporating the granules into a dosage form.

90. The process of claim 89,w herein the granules have a diameter from about 0.1 mm to about 3 mm.

91. The process of claim 89,w herein step (c) comprises incorporating the granules into a tablet.

92. The process of claim 89,w herein step (c) comprises incorporating the granules into a capsule.

93. The process of claim 89,w herein the dosage form is a matrix.

94. The process of claim 89,w herein step (a) further comprises mixing oxymorphone or a salt thereof with an alkylcellulose.

95. The process of claim 89,w herein step (a) further comprises mixing oxymorphone or a salt thereof with ethylcellulose.

96. The process of claim 89,w herein the dosage form provides a therapeutic effect for about 12 hours or more.

97. The process of claim 89,w herein the dosage form provides a therapeutic effect for about 24 hours or more.

98. A process of making a sustained-release dosage form comprising: (a) mixing oxymorphone or a salt thereof with a hydrophilic polymer, a binder, and a diluent; (b) subjecting the mixture to shear to form granules; and (c) incorporating the granules into a dosage form.

99. The process of claim 98,w herein the granules have a diameter from about 0.1 mm to about 3mm.

100. The process of claim 98,w herein step (c) comprises incorporating the granules into a tablet.

101. The process of claim 98,w herein step (c) comprises incorporating the granules into a capsule.

102. The process of claim 98,w herein the dosage form is a matrix.

103. The process of claim 98,w herein step (a) further comprises mixing oxymorphone or a salt thereof with alkylcellulose.

104. The process of claim 98,w herein step (a) further comprises mixing oxymorphone or a salt thereof with ethylcellulose.

105. The process of claim 98,w herein the dosage form provides a therapeutic effect for about 12 hours or more.

106. The process of claim 98,w herein the dosage form provides a therapeutic effect for about 24 hours or more.

* * * * *

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor of the subject matter which is described and claimed and for which a patent is sought on the invention entitled:

**ORALLY ADMINSTRABLE OPIOID FORMULATIONS HAVING EXTENDED
DURATION OF EFFECT**

the specification of which was filed on December 8, 2003 as Application No. 10/731,678 and amended on March 12, 2004; March 17, 2004; and July 20, 2006.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by an amendment, if any, specifically referred to herein. I do not know and do not believe that the same was ever known or used in the United States of America before my or our invention thereof or patented or described in any printed publication in any country before my or our invention thereof, or more than one year prior to this application, or in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigned more than twelve months prior to this application.

I acknowledge the duty to disclose all information known to me that is material to patentability in accordance with Title 37, Code of Federal Regulations, § 1.56.

FOREIGN PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

☒ no such foreign applications have been filed

☐ such foreign application have been filed as follows:

**EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

Application Number	Country	Date of Filing	Priority Claimed Under 35 USC 119
			____ Yes No ____
			____ Yes No ____
			____ Yes No ____

**ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

Application Number	Country	Date of Filing

CLAIM FOR BENEFIT OF EARLIER U.S. PROVISIONAL APPLICATIONS

I hereby claim priority benefits under Title 35, United States Code §119(e), of any United States provisional patent application(s) listed below:

☒ no such U.S. provisional applications have been filed.

☐ such U.S. provisional application have been filed as follows:

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		____ Yes No ____
		____ Yes No ____

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, §120 of the United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose all information that is material to patentability in accordance with Title 37, Code of Federal

Regulations, §1.56 which became available to me between the filing date of the prior application and the national or PCT international filing date of this application:

- ☐ no such U.S./PCT applications have been filed.
- ☒ such U.S./PCT application have been filed as follows:

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08/097,558	July 27, 1993	Patented
08/086,248	July 1, 1993	Abandoned
08/081,618	June 23, 1993	Patented
07/826,084	January 27, 1992	Patented
07/814,111	December 24, 1991	Patented

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint the practitioners under Customer Number

07278

jointly, and each of them severally, my attorneys at law/patent agent(s), with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the U. S. Patent and Trademark Office connected therewith.

Please mail all correspondence to **Customer Number 07278**, whose address is:

Darby & Darby P.C.
P.O. Box 5257
New York, New York 10150-5257

Full name of sole or first inventor Benjamin Oshlack	
Sole or first inventor's signature <i>B. Oshlack</i>	Date <i>12 April 2007</i>
Residence Boca Raton, Florida	
Citizenship Australia	
Mailing Address 350 South Ocean Boulevard, Apt. 3D Boca Raton, Florida 33432	

Full name of second inventor, if any Mark Chasin	
Second inventor's signature	Date
Residence Monroe, New Jersey	
Citizenship United States	
Mailing Address 3 Turnberry Drive Monroe, New Jersey 08831	

Full name of third inventor, if any Frank Pedi, Jr.	
Third inventor's signature	Date
Residence Yorktown Heights, New York	
Citizenship United States	
Mailing Address 2773 Hyatt Street Yorktown Heights, New York 10598	

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New York, New York 10150-5257

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Sole or first inventor's signature	Date
Residence Boca Raton, Florida	
Citizenship Australia	
Mailing Address 350 South Ocean Boulevard, Apt. 3D Boca Raton, Florida 33432	

Full name of second inventor, if any Mark Chasin	
Second inventor's signature 	Date 4/10/07
Residence Monroe, New Jersey	
Citizenship United States	
Mailing Address 3 Turnberry Drive Monroe, New Jersey 08831	

Full name of third inventor, if any Frank Pedi, Jr.	
Third inventor's signature	Date
Residence Yorktown Heights, New York	
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I hereby appoint the practitioners under Customer Number

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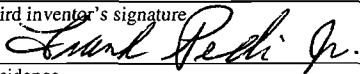
jointly, and each of them severally, my attorneys at law/patent agent(s), with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the U. S. Patent and Trademark Office connected therewith.

Please mail all correspondence to **Customer Number 07278**, whose address is:

Darby & Darby P.C.
P.O. Box 5257
New York, New York 10150-5257

Full name of sole or first inventor Benjamin Oshlack	
Sole or first inventor's signature	Date
Residence Boca Raton, Florida	
Citizenship Australia	
Mailing Address 350 South Ocean Boulevard, Apt. 3 D Boca Raton, Florida 33432	

Full name of second inventor, if any Mark Chasin	
Second inventor's signature	Date
Residence Monroe, New Jersey	
Citizenship United States	
Mailing Address 3 Turnberry Drive Monroe, New Jersey 08831	

Full name of third inventor, if any Frank Pedi, Jr.	
Third inventor's signature 	Date 04/05/07
Residence Yorktown Heights, New York	
Citizenship United States	
Mailing Address 2773 Hyatt Street Yorktown Heights, New York 10598	

Docket No.: 02755/0205241-US0
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Benjamin Oshlack et al.

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Art Unit: 1615

For: ORALLY ADMINSTRABLE OPIOID
FORMULATIONS HAVING EXTENDED
DURATION OF EFFECT

Examiner: M. Fitzgerald

**CONSENT OF ASSIGNEE IN SUPPORT OF PETITION
TO CORRECT INVENTORSHIP PURSUANT TO 37 C.F.R. 1.48(C)**

MAIL STOP PETITION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Philip C. Strassburger, hereby declare and state as follows:

1. I am Vice President, Intellectual Property Counsel at Purdue Pharma L.P., a limited partnership organized and existing under the laws of Delaware and having a place of business at One Stamford Forum, Stamford, Connecticut 06901-3431. I am an official empowered to act on behalf of Purdue Pharma L.P. and make these statements in that capacity.

2. Purdue Pharma L.P. is the assignee of all right, title and interest in and to this application by virtue of a chain of title from the original inventors Benjamin Oshlack and Mark Chasin. A Statement Under 37 C.F.R. 3.73(b) is submitted herewith, which sets forth the details of that chain of title, including the Reel and Frame numbers where each assignment in the chain

of title has been recorded and/or with a copy of the relevant assignment document(s) attached thereto.

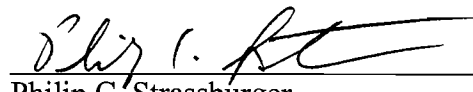
3. I understand that a Petition is being filed in the U.S. Patent and Trademark Office to amend the inventorship of this application. I understand, in particular, that this Petition seeks to add the name of Frank Pedi, Jr. as a co-inventor of this application.

4. I hereby give written consent, on behalf of the assignee Purdue Pharma L.P., for this change in the inventorship set forth for the application.

5. I further declare that all statement made herein of my own knowledge are true; that all statement made on information and belief are believed to be true. I understand that willful false statement and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or of any patent issuing therefrom.

Dated: April 16, 2007

Respectfully submitted,



Philip C. Strassburger
Vice President, Intellectual Property Counsel
Purdue Pharma L.P.
One Stamford Forum
Stamford, Connecticut 06901-3431
Tel. (203) 588-7639